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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/068,314	02/06/2002	Michael T. Trese	TMT-10902/04	8834

7590 12/01/2005

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EXAMINER

DESANTO, MATTHEW F

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 12/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/068,314	Applicant(s) TRESE ET AL.	
	Examiner Matthew F. DeSanto	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 13-21 and 24-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 13-21, 24-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. In view of the appeal brief filed on 8/22/05, PROSECUTION IS HEREBY REOPENED.


New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:


NICHOLAS D. LUCCHESI
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3763

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1, and 14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not

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described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In claims 1 and 14, the range that is being claimed is less than 0.4 units doesn't meet the description requirement because the phrase "less than" has no lower limit and caused the claims to read literally on embodiments outside the ".01-10" unit range that is supported in the specification, because the dose of the plasmin could be .0001 unit, which would cause the claim to incorporate new matter and fail to comply with the written description requirement. See MPEP section 2163.05, part III range limitations.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-7, 9, 10, 13-18, 20, 21, and 24 are under 35 U.S.C. 103(a) as being unpatentable over by Trese et al. (Ophthalmology, Volume 105, Issue 9, 1 September 1998, pages 1617-1620).

Trese et al. discloses the delivery of autologous human plasmin into a vitreous body of an eye and then incubating the eye. Trese et al. discloses using 0.4 IU, but fails to disclose a size of dose smaller than 0.4 IU.

AT the time of the invention it would have been obvious for one of ordinary skill in the art to modify the teachings of Trese et al. because it is well known in the medical field art to vary the dose size that will be injected into a patient, since medication usually depends on the size of the patient as well as the area in which the injection will occur. This concept is well known in the research art and can be seen in the previous cited prior art (Entire reference).

6. Claims 8, 19, 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trese et al. (Ophthalmology, Volume 105, Issue 9, 1 September 1998, pages 1617-1620) as applied to the claims above, and further in view of Trese et al. (American Academy of Ophthalmology, ISSN 1607-1610).

Trese et al. (Ophthalmology) discloses the claimed invention but fails to specifically point out the use of a plasmin inhibitor and the actual size of the needle being used to remove the liquefaction that occurred in the eye.

Trese et al. (American Academy of Ophthalmology) discloses the use of a plasmin for the liquefaction of the eye as well as the use of small gauge needles for sucking the material out of the eye (page 1610 2nd Column, 1st paragraph) and the use of a plasmin inhibitor to reduce to the activity of the plasmin that was injection into the eye (surgical techniques).

At the time of the invention it would have been obvious for one of ordinary skill in the art to combine the teachings of Trese et al. with Trese et al. because Trese et al. (American) provides further explanation as to why those steps are necessary. Trese et al. (American) also discloses the level of skill in the medical art since it is well known in the art to perform these steps.

Response to Arguments

7. Applicant's arguments filed on 8/22/05 have been fully considered but they are not persuasive.
8. With regards to streptokinase-plasminogen being produced in the Trese et al. prior art, and the arguments drawn to this rejection, the examiner disagrees because one of ordinary skill in the art would interpret the article to produce autologous plasmin since this is what is stated.
9. The examiner still keeps the rejections because the applicant is trying to get a patent on the method of liquefying the eye with a plasmin. This is taught in the prior art references.
10. The examiner is basing the rejections that it would have been obvious to change the size and concentration of the plasmin that would be injected in an eye. It is well known in the art to vary the concentration and size of a dose through routine and well-known experimentation procedures to see whether vitreous liquefaction of the eye will occur. The examiner determines that it would be obvious to vary the concentration and volume of a dose in an experiment, especially when performing research so that a conclusion can be reached with regards to the dose and concentration. Thus the examiner determines that normal experimentation with the prior art would make it obvious to have the concentration as claimed. The examiner would also like to note, that when treating a patient it is well known to vary a dose of a medicament depending on several factors, such as size of the patient, weight, sex, how easier the person is affected by the medicament as well as several other factors.
11. The examiner would also like to note that there is a lack of criticality to the size of the dose of plasmin. There is no evidence in the specification that 0.4 IU is critical for the invention

to work, and therefore the examiner determined that it would be obvious from the prior art references.

12. The examiner cites case law to further support his rejection based on the interpretations of optimization of ranges.

13. With regards to the optimization of ranges, the examiner would like to point out, that optimization within prior art conditions or through routine experimentation, generally, with differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955), as well as a particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. In re Antonie, 559 F.2d 618, 195 USPQ 6 (CCPA 1977).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F. DeSanto whose telephone number is 571-272-4957. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick LUCCHESI can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Matthew DeSanto
Art Unit 3763
November 26, 2005



NICHOLAS D. MOUCHEL
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3763